OCT 2 6 2001

K012410

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter, name, address, contact

Sigma Diagnostics Inc.
545 South Ewing Ave
St. Louis, MO 63103

Contact person: William R. Gilbert
(314) 286-6693

Date Prepared: July 26, 2001

2. Device name

Proprietary name: INFINITY™ HbA_{1c}

Common name: Hemoglobin A_{1c}

Classification name: Assay, Glycosylated Hemoglobin, 81 LCP, 21 CFR 864.7470

3. Predicate device

Roche Diagnostics HbA1c II K940082
Bio-Rad VARIANT™ II K984268

4. Device description

The INFINITY HbA_{1c} assay is a microparticle enhanced turbidimetric immunoassay.

5. Intended Use

Sigma Diagnostics INFINITY™ HbA_{1c} assay is an in vitro assay for the quantitative determination of hemoglobin A_{1c} (HbA_{1c}) in whole blood for use on automated analyzers.

6. Comparison to predicate devices

Characteristic	INFINITY™ HbA_{1c} (Candidate Device)	Bio-Rad VARIANT™ II (Predicate Device)	Roche Diagnostics HbA_{1c} II (Predicate Device)
Intended Use	For use in the quantitative determination of hemoglobin A_{1c} (HbA_{1c}) in whole blood on automated analyzers.	For use in the quantitative determination of hemoglobin A_{1c} (HbA_{1c}) in whole blood	For use in the quantitative determination of hemoglobin A_{1c} (HbA_{1c}) in whole blood on automated analyzers.
Format	Microparticle enhanced turbidimetric immunoassay	Cation exchange chromatography (HPLC)	Immunoturbidimetric
Sample Type	Human anticoagulated whole blood (EDTA or Heparin)	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA or Heparin)

The substantial equivalency of Sigma Diagnostics INFINITY™ HbA_{1c} (537-A, 537-B) to the Roche Diagnostics HbA_{1c} II and to the Bio-Rad Variant™ II Hemoglobin A_{1c}, is supported by the following facts:

1. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Cobas Mira and the Roche Diagnostics HbA_{1c} II on the Hitachi 717. The correlation coefficient was 0.976 and the regression equation was y = 0.9513x + 0.4184.

2. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Cobas Mira and the Bio-Rad Variant™ II Hemoglobin A_{1c}. The correlation coefficient was 0.981 and the regression equation was y = 1.047x – 0.5462.

3. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Hitachi 911 and the Roche Diagnostics HbA_{1c} II on the Hitachi 717. The correlation coefficient was 0.990 and the regression equation was y = 0.9639 + 0.5574.

4. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Hitachi 911 and the Bio-Rad Variant™ II Hemoglobin A_{1c}. The correlation coefficient was 0.981 and the regression equation was y = 1.046x - 0.2878.

5. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Hitachi 717 and the Roche Diagnostics HbA_{1c} II on the Hitachi 717. The correlation coefficient was 0.985 and the regression equation was y = 0.8988x + 0.9656.

6. %HbA1c was determined in 45 patient samples using the Sigma Diagnostics INFINITY™ HbA_{1c} on the Hitachi 717 and the Bio-Rad Variant™ II Hemoglobin A_{1c}. The correlation coefficient was 0.988 and the regression equation was y = 0.9877x + 0.0711.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics, Inc.
545 South Ewing Avenue
St. Louis, Missouri 63103

OCT 2 6 2001

Re: K012410
Trade Name: Sigma Diagnostics INFINITY™ HbA_{1c}
Regulation Number: 21 CFR § 864.7470
Regulation Name: Glycosylated Hemoglobin
Regulatory Class: II
Product Code: LCP
Dated: July 27, 2001
Received: July 30, 2001

Dear Dr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012410

Device Name: Sigma Diagnostics INFINITY™ HbA_{1c}

Indications For Use:

Sigma Diagnostics INFINITY™ HbA_{1c} is a device to measure the percent hemoglobin A_{1c} in anticoagulated whole blood. Hemoglobin A_{1c} is indicated for the monitoring of long-term glucose control in individuals with diabetes mellitus.

Sylvia Michaud for J. BAUTISTA

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012410

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR **Over-The-Counter Use** ____
(Per 21 CFR 801.109)